

73314-7

FEB 28 2014

Mr. Matthew Feinberg
 Authorized Agent for Novozymes BioAg, Inc.
 Exponent, Inc.
 1150 Connecticut Avenue NW, Suite 1100
 Washington, D.C. 20036

Re: Novozymes BioAg, Inc.; NoFly™ Technical
 EPA Registration No. 73314-7
 Minor Label and Formulation ("Fast Track") Amendment
 Submissions Dated 07/18/2013, 09/18/2013, 02/14/2014, and 02/24/2014
 Decision Nos. 481148 and 482147

Dear Mr. Feinberg:

In an application dated July 18, 2013 (Decision No. 481148), you, on behalf of Novozymes BioAg, Inc., notified the U.S. Environmental Protection Agency (EPA) that you updated particular information on the NoFly™ Technical label and confidential statement of formula (CSF) to account for a recent company transfer (EPA Company Number 73314) from Natural Industries, Inc., to Novozymes BioAg, Inc. In addition to the label updates related to the company transfer, you also added or modified Hot Line Number information to/in the First Aid box. Subsequently, the EPA determined that the modification of one mandatory statement (Pesticide Registration (PR) Notice 2000-5) in the Hot Line Number information did not fall under the scope of PR Notice 98-10 and therefore converted the notification to a minor label and formulation amendment (Decision No. 482147).

The EPA reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
- 2) Addition of language that explains the purpose of text and/or images found within curly and square brackets (i.e., comments to label reviewers or optional label items).

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
USERNAME	KAUSCH	Bauer	Wreni					
DATE	02/25/2014	2/25/14	2/28/14					

- 3) Replacement of "EPA Registration No.: 73314-T" with "EPA Registration No.: 73314-7"
- 4) Replacement of "Net Contents" with "Net Weight" as NoFly™ Technical is a solid (Chapter 17, Section III of the EPA's Label Review Manual – Revised November 2012).
- 5) Modification of the registrant's name and the registrant's contact information (e.g., street address) to reflect a recent company transfer.
- 6) Addition of several comments for label reviewers in curly brackets (e.g., "Batch code to be inserted").
- 7) Addition of or modification to Hot Line Number information in the First Aid box (Chapter 7, Sections III(F)(9) and III(F)(10) of the EPA's Label Review Manual – Revised July 2012).
- 8) Rearrangement of certain statements in the Hazards to Humans and Domestic Animals section to ensure that these statements are organized so that the routes of exposure of most concern, as supported by toxicity category classifications, are listed first (Chapter 7, Section III(D)(3) of the EPA's Label Review Manual – Revised July 2012).
- 9) Integration of the Personal Protective Equipment section into the Hazards to Humans and Domestic Animals section, since NoFly™ Technical is not subject to the requirements of the Worker Protection Standard.
- 10) Addition of the following statement to the Hazards to Humans and Domestic Animals section to align with standard text found on other microbial pesticide product labels:
"Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization."
- 11) Addition of more specific use information (for end-use pesticide products to be formulated from NoFly™ Technical) in the Directions for Use.
- 12) Adjustment of text in the Storage and Disposal box to align with information presented in Chapter 13 of the EPA's Label Review Manual (Revised July 2013) and to account for the intended packaging of the product (i.e., bags inside of boxes).
- 13) Modification of the Warranty section to reflect a recent company transfer.

Additionally, you updated the CSF on file for NoFly™ Technical. There is now only one valid CSF for this product registration: a basic formulation dated February 10, 2014. All previously accepted NoFly™ Technical CSFs have been superseded by the aforementioned CSF.

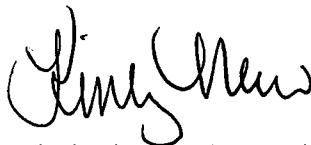
Matthew Feinberg
EPA Registration No. 73314-7

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (kausch.jeannine@epa.gov).

A stamped, accepted copy of the label is enclosed for your records.

Sincerely,



Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):

- NoFly™ Technical Stamped, Accepted Label
- A-79 Enclosure

Note to reviewer:

{ } – Denotes comments to the reviewer

[] – Denotes optional statements and/or images.

{Front panel}

NoFly™ Technical

For Manufacturing Use Only

ACTIVE INGREDIENT: *Paecilomyces fumosoroseus* strain FE 9901* 69.0%

OTHER INGREDIENTS: 31.0%

TOTAL: 100.0%

*Contains at least 8.1×10^9 colony forming units per gram (dry weight basis)

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for precautionary statements, first aid, directions for use and storage and disposal instructions.

EPA Registration No.: 73314-7

EPA Establishment No.: 73314-TX-001

Net Weight:

Novozymes BioAg, Inc.
13100 W. Lisbon Road, Suite 600
Brookfield, WI 53005
800-245-4104

ACCEPTED

FEB 28 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 73314-7

Batch code: {Batch code to be inserted}

Date of manufacture: {Date of manufacture to be inserted}

Use within six months of the date of manufacture.

{Back Panel}

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call your local poison control center at 1-800-222-1222.	

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin, swallowed, or inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash according to manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE) before reuse. If no such instructions are available, use clothing detergent and hot water for cleaning all washable PPE. Keep and wash PPE separately from other laundry. When handling this product, wear protective eyewear, either goggles, face shield, or shielded safety glasses; waterproof gloves; and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, P-95, or HE filter for biological products. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR MANUFACTURING USE ONLY. Only for formulation into registered end-use pesticide products for use as a mycoinsecticide in or on non-food plants. Formulators are responsible for obtaining EPA registration of their end-use pesticide products. Not for direct treatment of pests. Do not use from damaged, punctured or unsealed containers.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place. Do not freeze. Storage above 90°F for prolonged periods may impair activity. Keep container tightly closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into manufacturing equipment. Then, offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke. If outer box is contaminated, dispose of it in the same manner as required for its bag.

WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully. Novozymes BioAg, Inc. warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal conditions is reasonably fit for the purposes referred to above. Buyers/Users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above and to the extent consistent with applicable law, customer's sole remedy for breach of warranty shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes BioAg, Inc.

EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESSED REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESSED OR IMPLIED WARRANTY OR GUARANTEE TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, INCLUDING ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.